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Memorandum for

LES Officers, Trustees and Past Presidents

WASHINGTON SUMMARY

March 1982

Court of Appeals For the Federal Circuit

President Reagan signed H R. 4482 to create the CAFC on Friday, April 2, 1982. The act is now Public Law 97-164.

The sections of the new law of most immediate interest follow:

Effect on Pending Cases

Sec. 403. (a) Any case pending before the Court of Claims on the effective date of this Act in which a report on the merits has been filed by a commissioner, or in which there is pending a request for review, and upon which the court has not acted, shall be transferred to the United States Court of Appeals for the Federal Circuit.

(b) Any matter pending before the United States Court of Customs and Patent Appeals on the effective date of this Act shall be transferred to the United States Court of Appeals for the Federal Circuit.

(c) Any petition for rehearing, reconsideration, alteration, modification, or other change in any decision of the United States Court of Claims or the United States Court of Customs and Patent Appeals rendered prior to the effective date of this Act that has not been determined by either of those courts on that date, or that is filed after that date, shall be determined by the United States Court of Appeals for the Federal Circuit.

(d) Any matter pending before a commissioner of the United States Court of Claims on the effective date of this Act, or any pending dispositive motion that the United States Court of Claims has not determined on that date, shall be determined by the United States Claims Court.

(e) Any case in which a notice of appeal has been filed in a district court of the United States prior to the effective date of this Act shall be decided by the court of appeals to which the appeal was taken.

PTO Fees

On Thursday, April 1st, Senator Weicker introduced S. 2326 which contains a compromise on the fee proposals of the Administration (S. 2211). Co-sponsoring the bill were Senators Kennedy, DeConcini, Hatch and Thurmond. A copy of the introduction statement and bill text is enclosed.

Patent Term Restoration Act

On March 25, 1982, the Kastenmeier subcommittee reported S. 1937 to the full committee. During the course of the mark up eight amendments were adopted and two amendments were offered and defeated.

Mr. Kastenmeier offered six amendments which were briefly discussed and adopted en block:

(1) The extension of the patent term will accrue only to the "recipient of marketing approval" and not the "owner of record of the patent". Those developing a product under a patent license will have to contemplate the possible extension period in terms of their rights. Because there is no "recipient of marketing approval" in the regulatory processes under the Toxic Substances Control Act, the amendment makes extensions under that law impossible. This is apparently a staff error and presumably will be corrected;

(2) Several restrictions are placed on the duration of the potential extension. The seven year maximum is retained with a proviso that the extension may not go beyond twenty seven years from the date the first application for the patent in question is filed anywhere in the world. For regulatory review periods occurring in the second ten years from the filing of the earliest patent application, only one half of the period will be credited. Also, patent terms may not be restored for less than a one year period;

(3) That portion of the bill which defined the precise periods of regulatory review was redrafted. As to pharmaceuticals, the period for determining the length of the extension will begin with the initiation of "clinical testing on humans" as opposed to the filing of the IND application;

(4) The catchall provision of the bill was eliminated. Now only patents for food additives, pharmaceuticals, medical devices, and chemicals whose terms are interfered with by specified statutes will be eligible for extension;

(5) The bill as introduced provided for extensions to begin on the effective date of the act for products then in the regulatory review pipeline. The amendment gives extensions only for products covered by patents issued on or subsequent to the date of enactment. There will be a major effort to reverse this narrowing amendment in the full Judiciary Committee;

(6) The bill was amended to benefit the Airco Company which is a constituent of Mr. Kastenmeier's. The amendment is intended to apply only to a single past situation.

Mr. Railsback offered two amendments which were accepted. The first would allow the extension of process patents under certain circumstances involving regulatory review. The amendment is designed to allow Genentech and other genetic engineering operations to receive patent term extensions on process patents which are reviewed by the Food and Drug Administration. The second amendment is a special interest amendment for G D. Searle & Co. involving the product "aspartame". This amendment was added to the Senate passed bill (S. 255) on the floor by Senator Heflin.

Congressmen Gore and Waxman wrote to Chairman Kastenmeier several days before the mark up urging that the legislation not be moved out of subcommittee. They also suggested a number of amendments to the bill as pending. Two of those amendments were offered by Mr. Frank. Both were defeated. The first would exempt generic drug manufacturers from liability under any state, federal, or common law for copying the "size, shape, color or appearance characteristic" of a "drug product". The second would have created a proceeding in the FDA to determine if "reasonable diligence" was used by applicants to secure drug approval and if not the period of extension would be thus shortened.

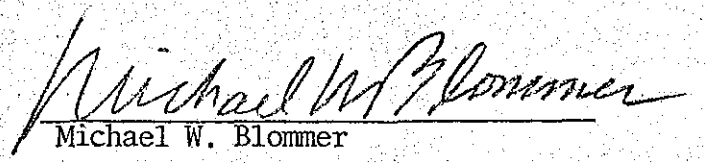
The amended version of H.R. 1937 will be brought before the full Judiciary Committee in the near future. Apparently, Messrs. Gore and Waxman are contemplating seeking a subsequent referral of the bill to the Committee on Energy and Commerce. If they are successful, the bill will not only be delayed but will reach the House floor either in two versions and with two committee reports or with the report of the second committee disapproving of the bill.

Manufacturing Clause

The copyright law now contains a requirement that nondramatic literary works be printed in the United States to receive full copyright protection. That provision expires on July 1, 1982. The Copyright Office recommends that the clause be allowed to expire. Congressman Ashbrook and Senator Thurmond have introduced bills (H.R. 3940 and S. 1880) on behalf of the printing industry to extend the clause permanently. They contend that failure to maintain the clause will mean a loss of American jobs.

The Reagan Administration, by the Deputy General Counsel of the U.S. Trade Representative, proposed that the Congress give the Executive Branch the blanket authority to terminate or retain the clause on a country by country basis using trade considerations as determinative factors. This "let us decide" proposal obviously had no political or substantive appeal for the subcommittee.

On March 17, 1982 Mr. Kastenmeier introduced H.R. 5870 which would extend the life of the manufacturing clause until July 1, 1985. On March 25, 1982 the Kastenmeier Subcommittee reported out H.R. 5870 to the full committee amended to extend the life of the clause until July 1, 1986.



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